



ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

DATE OUT: February 8, 2018

SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS
(830.6320) REVIEW
ACCELERATED STUDY ☒; ONE YEAR STUDY ☐;
OVER 1 YEAR STUDY ☐
MP ☐ EP ☒ EUP ☐
DP BARCODE No.: 435490 REG. No.: 53883-353
DECISION No.: 519917 MRID No: 499701-01
PRODUCT NAME: Quali-Pro® T-NEX®
COMPANY: CONTROL SOLUTIONS, INC:

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I. CONCLUSIONS:

FMC CORP. AGRICULTURAL PRODUCTS GROUP
STORAGE STABILITY (830.6317):
☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.310 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):
☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.310 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

The study reports indicate that the active ingredient did not quite meet the required statutory lower limit (i.e., an average of 11.33% when the statutory lower limit is 11.4%. It is recommended that Registrant submit a one year storage and stability study.

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II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes ☐ No

B. PRODUCT INFORMATION

Active ingredient: Trinexapac-ethyl

Label claims Nominal concentration (%): 12.0%

Initial concentration(s) of the AI(s) (%) used in the study: Averaged 11.91%

Lower certified limits (%) based on AI % in the study: 11.4%

C. EXPERIMENTAL PARAMETERS

Temperature: 54°C.

Relative Humidity:

Duration of study: 14 days.

Type of container: Fluorinated High Density Polyethylene bottles to simulate storage in commercial containers.

Analysis at intervals: ☒ 0 (initial); ☒ 2 weeks

D. ANALYTICAL METHOD

Method	DETECTOR
High Pressure Liquid chromatography (HPLC)	UV 240nm

E. RESULTS:

1. Compared to the initial concentration of the test substance the reported data shows that the AI% did not quite remain within the statutory parameters required in Title 40 CFR § 158.350 while stored at 54°C. The physical state of the test substance did not change. The test substance remained a transparent dark amber liquid and the container remained unchanged for 2 week testing period.
2. The HDPE containers were found to be compatible with the test substance.
3. The initial amount of the active ingredient found in the test substance was 11.91%; and the statutory lower limit is 11.4%. However, the amount of the active ingredients remaining at the end of the study was reported to have been 11.33%. Therefore, it is recommended that Registrant submit a one-year storage and stability study.